US ERA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

APR 1 7 1992

'MEMORANDUM

Subject:

Reregistration of Chlorpropham. Protocol for Potato

Post-Harvest Treatment Study.

DP Barcode D173558. MRID No. None. CBRS No. 9278.

From:

Stephen Funk, Ph.D., Chemist

Special Review Section I

Chemistry Branch II - Reregistration Support

Health Effects Division (H7509C)

Through:

Andrew Rathman, Section Head

Special Review Section I

Chemistry Branch II - Reregistration Support

·Health Effects Division (H7509C)

To:

Venus Eagle

Reregistration Section 1 Reregistration Branch Special Review and

Reregistration Division (H7508)

Background

The Reregistration Standard (08/19/87) and the Reregistration Standard Update (10/16/91) required processing studies for potatoes treated post-harvest with the sprout inhibitor isopropyl N-(3chlorophenyl) carbamate, or chlorpropham. Separate studies were to be conducted for potatoes treated on a conveyor belt with an EC formulation at 0.027 lb. a.i. per 1000 lbs. of potatoes, applied as a dilute aqueous spray, and for potatoes treated in commercial storage with a RTU formulation at 0.033 lb. a.i./1000 lbs. of potatoes, applied as an aerosol. Chlorpropham residues of concern were to be determined on potatoes analyzed immediately after Also, processing studies were to be conducted and chlorpropham residues of concern were to be determined in potato granules, potato chips, and potato peels (wet and dried). tolerance of 50 ppm exists for residues of chlorpropham (CIPC) and the metabolite hydroxyisopropyl N-(3-chlorophenyl) carbamate, calculated as CIPC (40 CFR 180.182).

E. R. Butts International, Inc. has submitted (01/23/92) a protocol entitled "Chlorpropham and 3-Chloroaniline Residue Study on Potatoes, Potato Skin, Potato Chips, and Potato Granules after Post-Harvest Fumigation." A protocol addressing both post-harvest treatments submitted by the Chlorpropham Task Force has been reviewed by CBRS (09/18/91 Memorandum, R. B. Perfetti, CBRS No. 8580).

Discussion

The formulation to be tested is Platt Chemical Co. Sprout Nip 7A, 34704-614, 7 lbs. chlorpropham a.i. per gallon. A single application will be made with a fogger to 5,000,000 pounds of potatoes stored in a 25 ft X 350 ft rectangular metal storage building in Rexburg, ID. The application rate will be 1 pound a.i. per 60,000 pounds of potatoes. Potato samples are to be taken from each of six sites in the potato pile. Two sites are at the top of pile, two are in the middle, and two are in the lower third of the Sixteen potatoes will be taken from each site (96 potatoes pile. per sampling interval) at the following intervals: 0, 4 hrs., 15 days, 30 days, 60 days, 90 days, and 120 days. Samples will be placed in metal cans and properly documented (study number, sample number, date collected, identity of sample, sample size, initials of collector, and location of collection). The potatoes from each site at each interval will be divided into the following processing groups: whole potatoes/wet skins, 5; dry potato skins, 3; potato chips, 3; potato granules, 5.

Samples will be transported to the laboratory within 24 hours of collection. The performing laboratory is identified as Analytical Laboratories, Inc. Potatoes to be processed into granules will be combined from each sampling interval (30 potatoes total) and will be sent directly to William J. Englar and Associates, Moses Lake, WA or to Granule Production Company, Inc., Boise, ID. The protocol specifies different processors in separate sections (A.III.h.; B.IV.d.) granules will be returned to The Analytical Laboratories, Inc. for analyses. A chain of custody will be maintained for the potato granule fractions. No mention is made of waste from the granule processing. Potato waste is an animal feed commodity and should be analyzed to determine chlorpropham residues.

All samples (66 potatoes per sampling interval) refrigerated in the laboratory. samples All will processed/analyzed within 5 days of collection. Each potato will be processed, extracted, and analyzed separately. Only the granule fraction potatoes are composited. Wet group potatoes will be individually peeled, and residues will be determined separately in each potato and skin. Each potato in the dry skin group will be individually peeled. The skins will be dried in an oven and each will be extracted and analyzed. Potatoes in the chip group will be individually peeled, sliced, fried, extracted, and analyzed.

Processing and extraction procedures are not described in this protocol.

The analytical procedure is provided in summary fashion only. Potato extracts are analyzed by hplc, utilizing a Barban internal standard.

Data will be collected in accordance with FIFRA GLP (40 CFR 160). The final report will include a description of all methods, any deviations from protocols, and details of the raw data.

Conclusions

The protocol is acceptable provided the following modifications are made:

- 1. The proposed application rate of 0.017 lb. a.i./1000 lbs. of potatoes is only 50% of the maximum allowed use rate of 0.033 lb. a.i./1000 lbs. (24(c)). The registrant must use the higher application rate or indicate nonsupport for the SLN registrations that permit the higher application rate.
- 2. Only fogger/aerosol application for storage purposes is addressed. Data must also be generated for potatoes (fresh or from storage) sprayed with chlorpropham prior to shipment. Processed fraction data are required from only one of the two application methods, but the potatoes processed must bear measurable residues of chlorpropham.
- 3. The parent and all regulated metabolites must be determined. At present, this means chlorpropham and hydroxyisopropyl N-(3-chlorophenyl) carbamate. Apparently, the analytical method determines chlorpropham and 3-chloroaniline. This may be acceptable if the registrant's procedure converts the metabolite to 3-chloroaniline prior to analysis. Clarification is required.
- 4. The analytical method summary states that Barban is added "...to each sample as an internal standard." This is acceptable only if the Barban is added to the final extract prior to analysis. It may not be used as an internal standard if it is added to the raw sample prior to extraction, i.e., internal standards may not be used to correct for poor extraction/workup efficiency.
- 5. Storage stability will not be required for those potatoes going directly to the laboratory, because preparation and analysis are to be conducted within 5 days of sampling. However, the time from sampling to processing into granules and the time from granule production to granule analysis are not specified. Each of these times must be less than about 10 days. Otherwise, storage stability data will be required for potatoes used to make granules and/or for potato granules.

- 6. The final report submitted to the Agency must contain typical chromatograms and associated raw data for each of the raw and processed commodities.
- 7. Conditions (temperature, humidity, light) of potato storage must be described in the final report and must conform to typical industry practice.
- 8. Details of the custom fogger operation must be described in the final report, including details of air recirculation rates through the stored potatoes for the 48 hours immediately after application.
- 9. CBRS recommends that the potato sampling schedule be amended to include sampling at about 48 to 72 hours (3 days) after treatment.
- 10. Potato waste from the granule processing should be analyzed also. Such waste is an animal feed commodity.
- 11. Processing (both laboratory and granule) must be described inthe final report. Extraction procedures must be detailed. Precautions should be taken during the laboratory peeling to prevent any transfer of residue from peel to potato flesh.
- 12. The final report must provide some detail of the sampling operation. The method used to obtain potato samples from the various levels of the pile must be explained.

Recommendation

CBRS recommends that the proposed protocol for treatment of potatoes in storage for purposes of determining residues of chlorpropham and its regulated metabolites in/on potatoes and processed potato commodities be accepted if the modifications noted in items numbers 1 - 12 above are instituted and that the registrant be advised to proceed with the study after effecting the changes.

RDI: A. Rathman:04/09/92:M. Metzger:04/09/92: H7509C:CBRS:S.Funk:305-5430:CM#2:RM803-A:SF(0492.1):04/08/92.

cc: RF, circ., Chlorpropham Reregistration Standard File, Chlorpropham SF, S. Funk, C. Furlow (PIB, FOD).